08/973,323

UNITED STATE EPARTMENT OF COMMERCE
Patent and Trad ark Office
Address COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY DOCKET NO

EXAMINER

ART UNIT	PAPER NUMBER
	10

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 9/4/98

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11, 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or ~~thirty days~~, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 36 - 70 is/are pending in the application.
Of the above, claim(s) 48-61, 63-65 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 36 - 47, 62, 66 - 70 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☒ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

* U.S. GPO: 1996-421-632 40,206

1. Applicant's election without traverse of Group I, claims 36-47, 62, 66-70 in Paper No. 9, filed 9/4/98 is acknowledged.

2. Claims 36-70 are pending.

Claims 48-61, 63-66, drawn to non-elected inventions, are withdrawn.

Claims 36-47, 62 and 66-70 are examined on the merits.

3. The use of various trademarks has been noted in this application. For example; Sephacryl S 300 (p. 10, line 27), Time Saver, Lambda zapII, Gigapack II, Sure, pBluescript, Sea Plaque GTG, GELase and Hybond-N (p. 19 lines 15-38). Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

4. The specification is objected to as not complying with 1.821(d) of the Sequence Rules and Regulations. When the description of a patent application discusses a sequence listing that is set forth in the "Sequence Listing" in accordance with paragraph (c) of the Sequence Rules and Regulations, reference must be made to the sequence by use of the assigned identifier, in the text of the description or claims of the patent application. Table 3 sets forth various sequences that are identified by the identifiers SEQ ID NO:6-10. The applicant is requested to amend the Table to include the appropriate (SEQ ID NO:) after its respective sequence. The Brief Description of Figures 18 and 20 discusses the sequences set forth in Figures 18 and 20. The applicant is advised to amend the descriptions of these two figures to recite the appropriate SEQ ID NO's. Appropriate correction is required.

5. Claims 38 and 70 are objected to as not complying with 1.821(d) of the Sequence Rules and Regulations. When the claims of a patent application discusses a sequence listing that is set forth

in the "Sequence Listing" in accordance with paragraph (c) of the Sequence Rules and Regulations, reference must be made to the sequence by use of the assigned identifier, in the text of the description or claims of the patent application. Appropriate correction is required.

6. Claim 38 is objected to because of the following informalities: It improperly depends from canceled claims 1 and 2. Appropriate correction is required.

7. Claim 36 is objected to because of the following informalities: It recites a trademark, "Sephacryl S300." The applicant is advised to amend the claim to recite the generic terminology.

8. Claims 36-47 and 68-70 are rejected under 35 U.S.C. § 101 because the claim is directed to non-statutory matter. The claimed protein has the same characteristics as naturally occurring proteins and therefore does not constitute patentable subject matter. In the absence of the hand of man the naturally occurring polyclonal antibodies are considered non-statutory subject matter. Diamond v. Chakrabarty, 206 U.S.P.Q. 193 (1980). The applicant is advised to amend the claims to claim an "isolated protein" or a "purified protein."

9. Claims 36-47, 62 and 66-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Overall, claim 36 is very confusing. It recites "has to comply with at least the features a), b), c), and d)," but the claim contains no items labeled a), b), c) or d). Thus, it is unclear which four of the seven features listed must be present in the claimed protein. Further, the various recitations of "at least" and "may be" are vague and indefinite. It is unclear what limitations define the claimed protein and must be present in the claimed protein. For example, how can the claimed protein comply ("has to comply with at least the features a), b)) with both the first two listed features, "may be isolated from murine ... cell lines" and "may be isolated from human ... cell lines?"

Claims 36, 39 are vague and indefinite in the recitation "may be isolated from." The claimed protein "may" (?but might not?) be isolated from the various cell types listed. The source of the claimed protein is thus unclear.

Claim 36 is vague and indefinite in the recitation "characteristic repeat structures." The identity of the characteristic repeat structure that defines the claimed product is unidentified.

Claim 36 is unclear in the recitation "the cDNA encoding the protein." Absent a designated cDNA sequence, the identity of the claimed cDNA is unclear.

Claim 36 is vague and indefinite in the recitation "corresponding mRNA species of different length consisting of identical 3' regions but different 5' regions." Likewise, claim 37 is vague and indefinite in the recitation "corresponding mRNA."

Claim 37 is vague and indefinite in the recitation "showing stable in vitro expression of the corresponding mRNA if allogenic spleen reaction is carried out with non-irradiated, not pretreated spleen cells of mouse strains CBA and C57Bl/6." It is unclear how such patterns of expression limit the claimed protein.

Claims 38 and 40 is vague and indefinite in the recitation "hybridizing." Absent limitations specifying specific stringency, the metes and bounds of the claimed DNAs are unclear. For claim

interpretation, the stringent hybridization conditions set forth on p. 6, lines 4-12 of the specification are interpreted to be the hybridization conditions of claim 41's "hybridizing ... under stringent conditions."

Claims 42 and 62 are vague and indefinite in the recitations "comprised portions, analogues, and derivatives of said proteins" (claim 42) and "an analogue, a derivative or portions thereof" (claim 62). It is unclear what constitutes an analogue or a derivative of said protein.

Claim 42 is vague and indefinite in the recitation "fusion proteins each coding for a protein." Fusion proteins do not code for proteins. Do only the fusion proteins have at least differentiation-inducing activity on Friend erythroleukemia cell lines, or do the portions, analogues, and derivatives of said proteins have only this single defining feature?

Claims 42, 47, 62, 66 and 67 are vague and indefinite in the recitation "having at least differentiation-inducing activity on Friend erythroleukemia cell lines" according to claim 36. If the claimed proteins have only this single defining property, " at least differentiation-inducing activity on Friend erythroleukemia cell lines," this is an improper broadening of scope of dependent claims depending from claim 36, which sets forth a longer listing of defining functional and physical features. Further, the overall expression "at least differentiation-inducing activity" in claims 36, 42, 45, 47, 62, 66 and 67. The specification sets forth only an erythroid differentiation assay. The specific activities one assays for with at least "differentiation-inducing activity" is unclear.

Claims 43 is vague and indefinite in the recitation "having essentially purified, native form." Claims 44 is vague and indefinite in the recitation "having essentially recombinant form. It is unclear what physical properties are imparted to the claimed protein in "native form" or "recombinant form."

Claim 45 is vague and indefinite in the recitation "having at least differentiation-inducing activity on Friend erythroleukemia cell lines and/or growth factor activity and/or colony-stimulating activity." Specifically, the recitations "and/or" are unclear. Must the claimed protein possess all three stated properties ("and") or only one of the listed properties ("or")?

Claim 47 is vague and indefinite in the recitation "having at least differentiation-inducing activity on friend erythroleukemia cell lines." Is the claim drawn to the protein of claim 36, which is further altered by "one or more of the amino acids may be deleted, substituted, or added" with the only remaining defining functional property being "having at least differentiation-inducing activity on friend erythroleukemia cell lines," and thus the elimination of the other functional and physical properties recited in claim 36?

Claim 62 is vague and indefinite in the recitation "therapeutic means." Is the claim drawn to a therapeutic composition or to a therapeutic treatment method?

Claim 62 is vague and indefinite in the recitation "effective amount." Effective amount for what purpose?

Claim 66 is vague and indefinite in the recitation "the human or murine protein with at least .... activity." Does the claimed "fusion protein" have the recited activity, or merely the original human and murine proteins, prior to constructing the fusion protein?

Claim 67 is vague and indefinite in the recitation "synthetic protein." The distinguishing characteristics of a "synthetic protein" are unclear. The various recitation of "at least" are also vague and indefinite. The applicant is advised to amend the claims to recite open language, "comprises," were appropriate.

Claim 68 is vague and indefinite in the recitation "or inhibitors of said protein." The metes and bounds of the claim cannot be determined. An "inhibitor" can be anything; a peptide, an organic molecule, an inorganic molecule, a DNA fragment, a plastic, a carbohydrate, etc. Applicant's attention is directed to Ex Parte Tanksley (26 USPQ2d 1384) wherein the Board noted that under 35 U.S.C. 112, second paragraph, the claims must be so definite as to allow the comparison with the available art and must also make it possible for the public to determine from the claims what they encompass. How would one know if the patented claimed was being infringed?

Claim 68 is vague and indefinite in the recitation "for the treatment of diseases in which local or systemic overproduction or underproduction of this protein affects the development of the disease or the course thereof." It is unclear how the stated intended use of the protein further

ses, the stated intended use is given no
d indefinite as no specific disease is

olony-stimulating factor, a factor inducing
claim 69 is directed to an intended use of the
urther limits the claimed protein. For
atentable weight.
ion "said protein comprises at least those
or 155-685. Absent the recitation of a
ts SEQ ID NO), the identity of the claimed
is unclear.

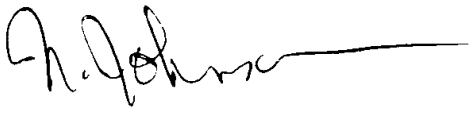
U.S.C. 112, first paragraph, because the
r, a protein that induces differentiation in
rmation, comprising an amino acid sequence
y provide enablement for the broadly
ny person skilled in the art to which it
make and use the invention commensurate
of the claims, as discussed in the above
s that define the claimed protein are unclear
can not make and use the claimed protein,
asonable expectation of success and without

e paragraphs of 35 U.S.C. 102 that form the
s Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 36, 37, 39, 42-47, 62, 66, 68-70 are rejected under 35 U.S.C. 102(b) as being anticipated by any of WO 89/04668, Eto (BBRC 142:1095, 1987) or Tsuji (Biotechnology and Bioengineering 31:675, 1988). All three references disclose a protein that is the same as that claimed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Johnson whose telephone number is (703) 305-5860. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014 or (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Nancy A. Johnson, Ph.D.
Patent Examiner, Group 1642
December 4, 1998